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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/758,036 | 01/11/2001 | Ekkehard Leberer | 38005-0126 | 8288 |

26633 7590 01/28/2004

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EXAMINER

LAMBERTSON, DAVID A

| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------|--|---------------------------------------|--|
| Advisory Action | Application No. 09/758,036 | Applicant(s) LEBERER ET AL. | |
| | Examiner David A. Lambertson | Art Unit 1636 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 28 July 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-11 and 19-21.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 2. NOTE: Applicant's amendment after final has not been entered because the amendment requires a new search and consideration. Specifically, Applicant has added an additional claim, which encompasses limitations that had not been searched in a previous Office Action. Newly added claim 25 introduces the limitation "wherein the eukaryotic potassium channel is a Kir2.1 or IRK1," which was not previously present in the claims searched prior to the First or Final Office Actions issued by the Office. Therefore, this limitation requires a new search and consideration with regard to the patentability of the application. Because this limitation requires a new search and consideration, and because prosecution on the merits is closed, the After Final amendment is not entered.

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's arguments regarding the withdrawal of FINALITY and the rejection of claims 1-11 and 19-21 under 35 USC § 103(a) are not persuasive, and are addressed in a point-by-point fashion below.

Applicant argues that the FINAL Office Action was improper because the new rejections that were raised could have been raised in the previous Office Action. Applicant's arguments are not convincing because the claims that are in question regarding the new rejections, specifically claims 4-11 and 19, were not even considered on the merits in the first Office Action. Applicant is direct to MPEP § 608.01(n), specifically section F (Handling of Multiple Dependent Claims by the Examiner), where it states that improper multiple-dependent claims should not be treated on the merits. It was clearly set forth in the first Office Action that claims 4-11 and 19 were not being treated on the merits; therefore, there could not have been a rejection of these claims in the first Office Action. The consideration of the claims required an amendment to place them in the proper dependency. It was not until the claims were amended to correct their dependency that the claims were treated on the merits; therefore, the rejection of the claims following the amendment can properly be made FINAL, being based on the amendment which allowed them to be considered on the merits. As a result, the rejection of these claims upon their amendment could indeed be made FINAL, thus the FINALITY of the previous Office Action is maintained as proper.

With regard to the rejection of claims 1-11 and 19-21 under 35 USC 103(a), Applicant presents the argument that the ordinary skilled artisan would have been "led away from the teachings of Fairman" because of the following facts:

1. Fairman suggests and demonstrates that the triple deletion strain (trk1 trk2 tok1) grows worse than the double deletion strain (trk1 trk2), thus one of skill in the art would presume that the triple deletion is more pathologic than the double deletion.
2. Applicant asserts in their specification that the more pathologic phenotype is not better complemented by the expression of heterologous proteins, pointing to their own specification (specifically, page 3, lines 9-12) and stating that the human channels HERG1 or Kv1.5 cannot complement the double deletion (trk1 trk2).
3. From this, applicant hypothesizes that one of skill in the art would not expect those channels to be able to complement the more pathologic triple deletion (trk1 trk2 tok1) because, if it does not complement the "healthier" phenotype of the double deletion strain, there is no reason to believe it would complement the "weaker" phenotype of the triple deletion strain. Therefore, Applicant asserts that the skilled artisan would not combine the teachings with any expectation of success based upon the disclosure set forth in the instant specification that not all heterologous potassium ion channel genes are capable of complementing the double deletion strain.

Applicant's arguments are not persuasive for the following reasons:

First, there is no teaching in any of the prior art references to indicate that the HERG1 or Kv1.5 heterologous potassium ion channels would not complement the double or triple deletion strains. As such, there is nothing in the prior art references that "teaches away" from the instant invention. Applicant is relying on the findings of the instant specification, which absent an indication from applicant, cannot be construed as prior art. Therefore, Applicant cannot insert their findings into the prior art in order to establish that the independent references "teach away" from the instant invention. This would seem to be more of an "unexpected results" argument than a "teaching away" argument (see below).

Second, it is clear that not all heterologous potassium ion channels have such trouble complementing the double deletion phenotype, as claimed by Applicant in their arguments. This is evident from the Tang et al. reference, which indicates that the gpiRK1 gene does indeed complement the double deletion strain. Thus, there can be no absence of a reasonable expectation of success with regard to the basis of Applicant's arguments because, unlike HERG1 and Kv1.5, gpiRK1 does complement the double deletion strain. Therefore, one of ordinary skill in the art would have no reason to doubt the expression of gpiRK1 in the triple deletion, even if the instant specification was prior art.

With regard to Applicant's potential position on "unexpected results," Applicant is reminded that when arguing unexpected results, there must be a demonstration that the unexpected results are commensurate in scope with the claimed invention. See MPEP § 716.02(d)[R-1]. In the instant case, even if it is assumed that HERG1 and Kv1.5, when expressed in the triple deletion strain, presents an unexpected result in that it rescues the triple but not the double deletion strain, this is not commensurate in scope with the instant claims. The claims are much broader than the species for which an "unexpected result" exists. Indeed, even in the dependent claim which recited HERG1 and Kv1.5 as specific species to be used in the claimed method, a species is present (gpiRK1) that conflicts with the "unexpected results" argument set forth for HERG1 and Kv1.5. This is because gpiRK1 does rescue the double deletion strain, therefore there is no rationale as to why it would not work similarly in the triple deletion strain.

In conclusion, Applicant's arguments are not convincing. The reliance on a non-prior art document, especially one that is not even mentioned in the rejection, cannot be used to establish an issue of "teaching away." There is nothing that is pointed to in any of the references recited in the instant rejections that indicates that performing the assay in the triple deletion strain would not work. With regard to the potential "unexpected results" (it appears that this is what Applicant is really arguing), these must be commensurate with the scope of the claims. This is clearly not the case because the scope of heterologous potassium ion channels that can be used in the assay is much broader than the HERG1 and Kv1.5 species which Applicant asserts can unexpectedly rescue the triple deletion strain, although they cannot rescue the double deletion strain. In fact, the scope includes a species that does indeed rescue the double deletion strain (gplRK1), and therefore cannot be subject to Applicant's argument that, "If it doesn't work in the double deletion, there's no reason to think it would work in the triple deletion." As a result, the rejection under 35 USC § 103(a) is maintained for the reasons set forth in the previous Office Actions, and the FINALITY of the rejection is maintained.



JAMES KETTER
PRIMARY EXAMINER